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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,829

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Motoo Sumida

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EXAMINER

CUTLIFF, YATE KAI RENE

ART UNIT

PAPER NUMBER

1621

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,829	Applicant(s) SUMIDA ET AL.	
	Examiner YATE' K. CUTLIFF	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8-21,24 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) 8-14,19,20 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,15-18,21,24,27 and 29-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1, 4, 5, 8-21, 24, 27-35 are pending.
Claims 2, 3, 6, 7, 22, 23, 25 and 26 have been canceled
Claims 8-14, 19, 20 and 28 have been withdrawn.
Claims 1, 4, 5, 15 – 18, 21, 24, 27 and 29 – 35 are rejected.

Claim Objections

2. Claims 15 – 19 are objected to for not depending upon a preceding claim 21. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim. A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Response to Arguments

3. Applicant's arguments, see pages 3 - 10, filed May 20, 2009, with respect to the rejection(s) of claim(s) 1, 4, 5, 15 – 18, 21, 24, 27, 29 and 31 – 35 under 35 USC 103(a) have been fully considered and are persuasive because the Williams reference does not clearly disclose the purified monoester of astaxanthin. However, upon further consideration, a new ground(s) of rejection is made in view of Kuniaki, et al. (JP 01-202261), Yukihiisa et al. (JP 11-290094) and Kleinig (Univ. Heidelberg, 1967) as set out below.

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4. The Examiner notes that a formal rejection to claim 30 was not provided in the Office Action mailed February 20, 2009.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 1, 4, 5, 15-18, 21, 24, 27 and 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuniaki, et al. (JP 01-202261, English translation), Yukihiisa et al. (JP 11-290094, English translation) and Kleinig (Univ. Heidelberg, 1967, abstract).

9. The rejected claims 1, 4 and 5 cover, inter alia, a purified astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 10 carbon atoms. Further, the medium chain fatty acid can have an even number of carbon atoms or have 8 carbon atoms.

10. Rejected claims 15-18, 21, 24, 27 and 29-35 cover, inter alia, a food composition, an animal feed, food additive or a cosmetic containing an astaxanthin medium-chain fatty acid monoester with a fatty acid having 8 to 10 carbon atoms.

11. Kuniaki et al. discloses a process for preparing esters of astaxanthin using a conventional method of esterifying alcohols by esterifying the hydroxyl groups of the astaxanthin using lower fatty acids. (see abstract). In Example 3 of the process caproic acid (C6:0) was used in the reaction process. The process of Kuniaki et al. produced esters of astaxanthin that was used as an additive to feed for fish. (see page 2 para. 5).

12. The difference between Kuniaki et al. and Applicant's claimed invention is as follows: use of the monoester as food composition by mixing food, and use of the monoester with a cosmetic composition; and C8 to C10 fatty acid monoesters of astaxanthin.

13. However, with regard to the use of monoesters of astaxanthin as food, the Examiner turned to the teachings of Yukihiisa et al. The Yukihiisa et al. reference discloses a process for preparing fatty acid monoesters of astaxanthin in an

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esterification reaction with fatty acids having 14 to 22 carbon atoms and lipase. (see [0001]). The esters produced can be used for food, and cosmetics. (see [0004]). It is stated that monoesters of astaxanthin is more stable than free astaxanthin and have superior absorption efficiency in the enteric canal (The gut; a tube concerned with digestion and absorption of food. In most animals it has one opening (mouth) into which food is taken and another (anus) from which unassimilated material is rejected.). (see page 8, [0005]). Further, in the reaction process of Yukihiisa et al. it is suggested that the ratio of fatty acid to free astaxanthin is less than 2 times mole, a high content of fatty acid diesters cannot be attained. (see [0013]). One of ordinary skill in the art would reasonably expect that when the fatty acid to free astaxanthin is less than 2 times mole that the reaction product would have a higher monoester yield. This conclusion is support by Yukihiisa's Table 2.

The Yukihiisa's reference does not specifically teach the use of fatty acids with C8 to C10 in their esterification process but from the combined teachings of Kuniaki et al. and Yukihiisa et al. one of ordinary skill in the art would reasonably expect that any conventional method used to esterify alcohols and fatty acids could be used to esterify the hydroxyl group of astaxanthin with medium-chain fatty acids. Further, the teaching of Kleinig discloses that astaxanthin, via the hydroxyl groups were esterified with myristic (C14), lauric (C12) and capric (C10) acids. (see abstract).

The only differences between the combinations of the references of Kuniaki, et al., Yukihiisa et al. and Kleinig is a monoester having C8 carbon atoms, However, the C8 (caprylic) fatty acid is between the caproic (C6) fatty acid used in the reaction

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process of Kuniaki et al. and the capric (C10) used in the esterification process of Kleinig. Thus, based on the teachings of these references, one of ordinary skill in the art would expect that a caprylic acid (C8) could be substituted in any of the esterification reactions of Kuniaki, et al., Yukihiisa et al. or Kleinig and produce a C8 monoester of astaxanthin. Therefore, the preparation of a fatty acid monoester of astaxanthin wherein the fatty acid has C8 to C10 carbon atoms can be affected via routine experimentation by the ordinary artisan skilled in the art. When the general condition of a claim are disclosed in the prior art, it is not inventive to discover optimum of workable ranges by routine experimentation. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

14. With regard to applicant's claim that the astaxanthin monoester is a purified form, Applicant has provided no information on the levels of purity so to ascertain a difference between their claimed product and one that can be easily produced by any of the processes disclosed in the references; Kuniaki, et al., Yukihiisa et al. and Kleinig. The factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or **suitable methods of obtaining that form or structure.** (In re Cofer, 354 F.2d 664, 148 USPQ 268 (CCPA 1966)). Furthermore, when claiming a purer form of a known compound, it must be demonstrated that the purified material possesses properties and utilities not possessed by the unpurified material. (Ex parte Reed, 135 USPQ 34, 36

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(Bd. Pat. App. & Int. 1961). In this instance the references Kuniaki, et al. and Yukihiisa et al. disclose conventional methods for preparing monoesters of astaxanthin using fatty acid esters at different ends of a homologous series of fatty acids (i.e. C6 and C14); with Kleinig using a C10 fatty acid to esterify the astaxanthin. Both of the references of Kuniaki, et al. and Yukihiisa et al. disclose the fact that esters of astaxanthin are suitable for use in food. Thus, one of ordinary skill in the art at the time of Applicant's claimed inventions would expect that monoesters of astaxanthin of medium-chain fatty acids (C8 and C10) possess the same properties as any close homologs of the series.

An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties. Where prior art compounds essentially bracket the claimed compounds and are well known pesticides, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new pesticides. (In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). In this instance, the references of Kuniaki, et al., Yukihiisa et al. and Kleinig discloses esters that bracket the monoesters of Applicant's claimed compound.

Therefore, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made, would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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